Stroke Team Remote Evaluation Using a Digital Observation Camera in Arizona (STRokE DOC): *The Initial Mayo Clinic Experience (TIME)*

Bart M. Demaerschalk, MD, MSc, FRCP(C) and Bentley J. Bobrow, MD for the STRokE DOC Arizona TIME Trialists

MAYO CLINIC

Mayo Clinic Hospital, Phoenix, Arizona, USA

Background and Purpose: There is a shortage of stroke specialist care in rural communities.[1-2] To address the under-utilization of acute stroke therapies, telemedicine techniques can be employed. Efficacy of site-independent telemedicine was originally assessed in the STRokE DOC trial in the state of California.[3] Telemedicine consultations resulted in more accurate decision making compared with telephone consultations.[3-4]

Objective: The main objective of **STRokE DOC AZ TIME** trial was to determine the feasibility of establishing a single hub, multi-rural spoke hospital telestroke research network in Arizona by replicating the **STRokE DOC** trial. Additionally, the purpose was to determine the effectiveness of telemedicine and telephone for decision making in acute stroke consultations in a different state among different hospitals and providers.

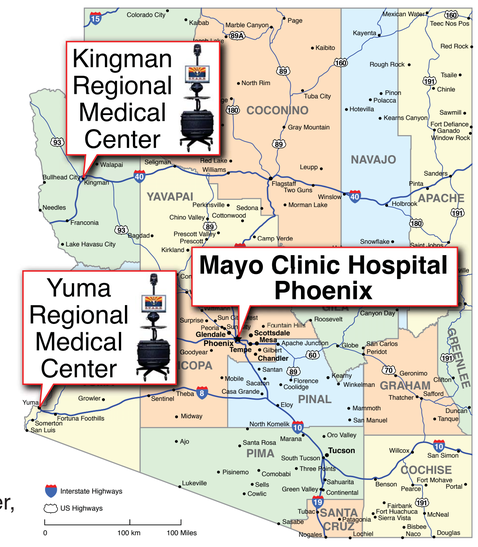
Design: The design was a prospective, single hub, two spoke, randomized, blinded, controlled trial of a 2-way, site-independent, audiovisual telemedicine system designed for remote examination of patients with acute stroke symptoms and signs versus telephone consultation to assess eligibility for treatment with intravenous thrombolysis.

Interventions: The consultative modes were telemedicine (real-time, two-way audio and video, and digital imaging and communications in medicine [DICOM] interpretation) versus telephone-only.

Population: The subjects were adults who presented to a rural Arizona hospital spoke emergency department with an acute stroke syndrome. The sample size was 54 subjects, (27 in video camera/ telemedicine intervention arm and 27 in the telephone-only arm).

Statistical Analysis: Fisher's exact test was used for the primary outcome, rate of thrombolytic use, rate of intracranial hemorrhage, mortality, 90-day modified Rankin scale score, and the Wilcoxan rank sum test was used for 90-day Barthel index and time point comparisons.

Results: The trial hotline was activated 84 times, 79 patients were eligible, 55 subjects consented, and 54 underwent randomization. The main results are presented in the tables and figures. Two spokes participated in 17 (63%) and 10 (37%) of the consultations, respectively. Twenty emergency physicians requested consultations: 8 (40%) 1 consult, 7 (35%) 2-5 consults, 5 (25%) initiated > 5 consults. Four hub neurologists performed 31 (57%), 13 (24%), 9 (17%), and 1 (2%) respectively of the 54 (100%) consults. Technical observations were noted in 20 (74%) of the telemedicine and 0 (0%) of the telephone-only consultations. None prevented determination of a treatment decision. Only 3 (6%) patients were discharged with a diagnosis other than stroke or TIA.



Hub Site: Mayo Clinic Hospital, Phoenix
Spoke Sites: Kingman Regional Medical Center, Yuma Regional Medical Center

Figure 1. **STRokE DOC Arizona TIME Trial Sites**

Figure 2. **Stroke Code Times**

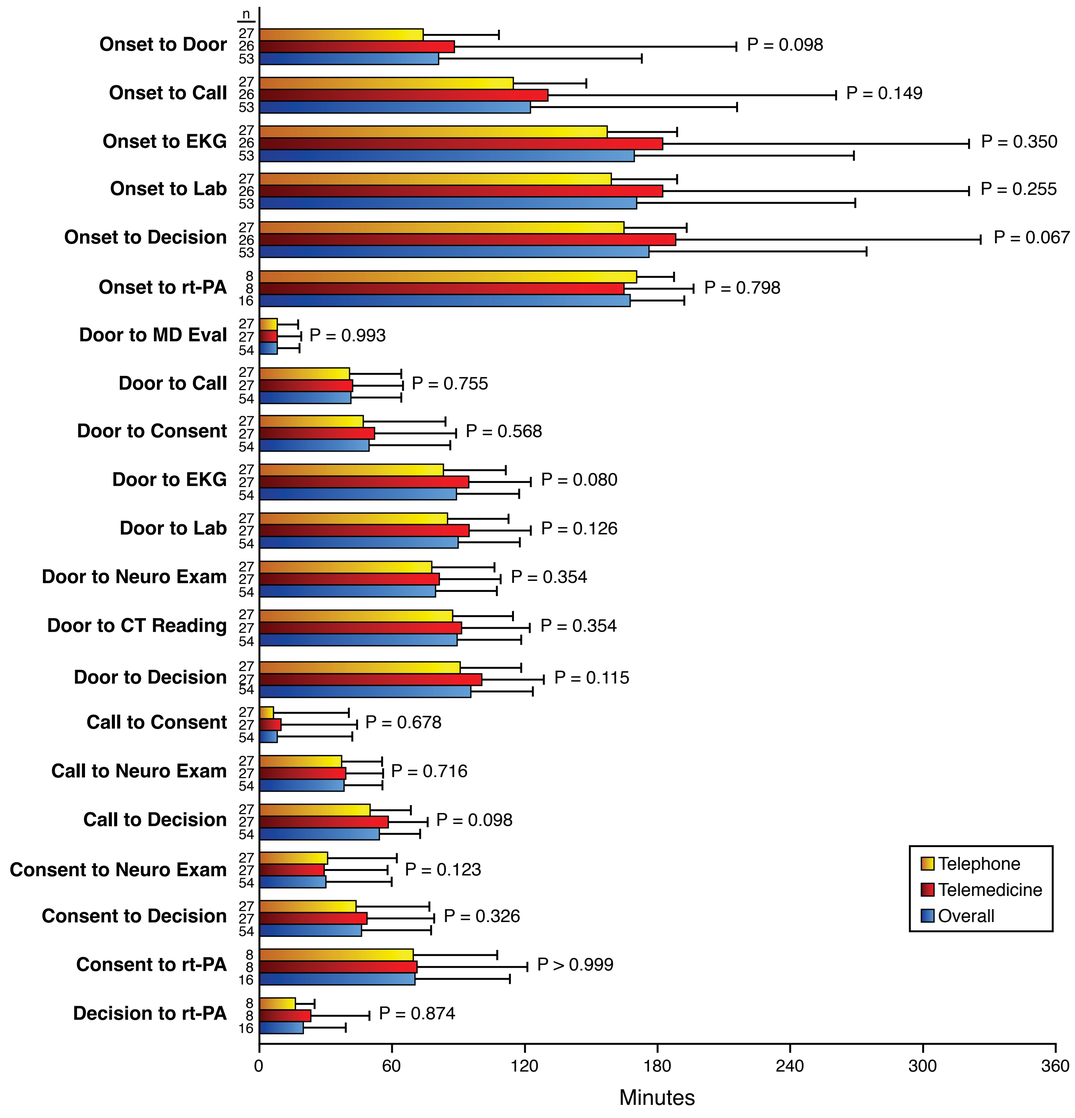


Table 1. Patient Characteristics

Patient Characteristics	Overall (n = 54)	Telemedicine (n = 27)	Telephone (n = 27)	P Value	Estimate (95% CI)
Age (years) Mean ± SD	66.3 ± 13.5	66.4 ± 13.6	66.1 ± 13.6	> 0.9999	0.3 (-6.95, 7.55)[a]
Female, n (%)	27 (50)	13 (48)	14 (52)	> 0.9999	1.16 (0.35, 3.85)[b]
Weight (kg) Mean ± SD	84.7 ± 19.7	88.2 ± 18.8	80.9 ± 20.3	0.4884	7.3 (-3.14, 17.74)[a]
Race, n (%)					
White	52 (96)	26 (96)	26 (96)	> 0.9999	
Black	2 (4)	1 (4)	1 (4)		
Not Hispanic, n (%)	47 (87)	23 (85)	24 (89)	> 0.9999	1.38 (0.21, 10.49)[b]
Risk Factors, n (%) & (% unknown)					
Coronary Disease	16 (30) (6% unknown)	11 (41) (4% unknown)	5 (19) (7% unknown)	0.2296	
MI	10 (19) (9% unknown)	9(33) (7% unknown)	1(4) (11% unknown)	0.0183	
Prior CVA	14 (26) (2% unknown)	8 (30) (0% unknown)	6 (22) (4% unknown)	0.7570	
Atrial Fibrillation	10 (19) (6% unknown)	5 (19) (4% unknown)	5 (19) (7% unknown)	> 0.9999	
Diabetes	14 (26) (4% unknown)	6 (23) (0% unknown)	8 (30) (7% unknown)	0.3224	
Hypertension	40 (74) (2% unknown)	22 (82) (0% unknown)	18 (67) (4% unknown)	0.3520	
Hyperlipidemia	19 (35) (11% unknown)	10 (37) (7% unknown)	9 (33) (15% unknown)	0.8528	
Fam Hx: Stroke/TIA	6 (11) (60% unknown)	4 (15) (67% unknown)	2 (7) (52% unknown)	0.2188	
Present Alcohol Use	6 (11) (41% unknown)	2 (7) (33% unknown)	4(15) (48% unknown)	0.4036	
Present Tobacco Use	14 (26) (15% unknown)	8(30) (7% unknown)	6 (22) (22% unknown)	0.4444	

[a]Difference in means; [b]Odds Ratios; CI = Confidence Interval

Table 2. Baseline Stroke Severity

Baseline Stroke Severity	Overall (n = 54)	Telemedicine (n = 27)	Telephone (n = 27)	P Value	Estimate (95% CI)
Pre-Stroke mRS (Complete Scale) n (%)					
Dichotomized (0-1)	46 (85)	23 (85)	23 (85)	> 0.9999	1.0 (0.16, 6.07)[a]
0 = No symptoms	42 (78)	20 (74)	22 (82)		
1 = No significant disability	4 (7)	3 (11)	1 (4)		
2 = Slight disability	5 (9)	3 (11)	2 (7)		
3 = Moderate disability	3 (6)	1 (4)	2 (7)		
4 = Moderate to severe disability	0 (0)	0 (0)	0 (0)		
5 = Severe disability	0 (0)	0 (0)	0 (0		
Baseline mRS (Complete Scale) n (%)					
Dichotomized (0-1)	6 (11)	3 (11)	3 (11)	> 0.9999	1.0 (0.12, 8.24)[a]
0 = No symptoms	2 (4)	1 (4)	1 (5)		
1 = No significant disability	4 (7)	2 (7)	2 (7)		
2 = Slight disability	8 (15)	3 (11)	5 (19)		
3 = Moderate disability	11 (20)	6 (22)	5 (19)		
4 = Moderate to severe disability	25 (46)	13 (48)	12 (44)		
5 = Severe disability	4 (7)	2 (7)	2 (7)		
NIHSS Mean ± SD (Median)	7.3 ± 6.2 (5.5)	7.1 ± 5.7 (5)	7.6 ± 6.7 (6)	0.8214	-0.5 (-3.82, 2.82)[b]
mNIHSS Mean ± SD (Median)	5.2 ± 5.3 (3)	5.3 ± 5.2 (3)	5.1 ± 5.6 (3)	0.8892	0.2 (-2.68, 3.08)[b]
Baseline CT n (%)					
Scan Normal	16 (30%)	7 (26%)	9 (33%)	0.7664	0.71 (0.18, 2.64)[a]
Primary ICH*	1 (2%)	1 (4%)	0 (0%)	> 0.9999	1.0 (0.07, 14.80)[a]
CT Contraindication to rt-PA	4 (7%)	2 (7%)	2 (7%)	> 0.9999	
rt-PA subset NIHSS (Mean ± SD)	12.2 ± 7.6	12.6 ± 6.1	11.8 ± 9.2	0.6355	0.8 (-6.85, 8.45)[b]
rt-PA subset mNIHSS (Mean ± SD)	9.1 ± 6.7	10.1 ± 5.6	8.0 ± 7.8	0.4910	2.1 (-4.55, 8.75)[b]

[a]Odds Ratios; [b]Difference in means; *No Odds Ratio due to sparse data; CI = Confidence Interval

Table 3. Results

Analyses	Telemedicine	Telephone	Odds Ratio (95% CI)	P Value*
Overall	n = 27	n = 27		
Correct Decision				
Level 2b (SDAC) (Primary)	**85%**	**89%**	**1.38 (0.21, 10.49)**	**> 0.999**
Level 1 (SDAC)	89%	89%	1.0 (0.12, 8.24)	
Level 2a (MM)	93%	100%	‡	> 0.999
Level 3a (MM)	93%	100%	‡	0.491
Level 3b (SDAC)	85%	96%	‡	0.491
Overall IV rt-PA treatment	30% (n = 8)	30% (n = 8)	1.0 (0.26, 3.78)	0.351
Overall Post Consult ICH	4% (n = 1)	0% (n = 0)	‡	> 0.999
90d BI (95-100)	59% (n = 13/22)	58% (n = 14/24)	1.0 (0.27, 3.92)	> 0.999
90d mRS (Dichotomized 0-1)	46% (n = 10/22)	38% (n = 9/24)	1.4 (0.37, 5.29)	0.765
Overall Mortality	4% (n = 1)	11% (n = 3)	‡	0.610
+rt-PA Subgroup	n = 8	n = 8		
Correct Decision				
Level 2b (SDAC) (Primary)	63%	88%	3.84 (0.23, 251)	0.569
Level 1 (SDAC)	89%	89%	1.0 (0.01, 89.5)	> 0.999
Level 2a (MM)	75%	100%	‡	0.467
Level 3a (MM)	75%	100%	‡	0.467
Level 3b (SDAC)	63%	88%	3.84 (0.23, 251)	0.569
Post rt-PA ICH	13% (n = 1)	0% (n = 0)	‡	> 0.999
90d BI (95-100)	57% (n = 4/7)	29% (n = 2/7)	3.04 (0.24, 55.3)	0.592
90d mRS (Dichotomized 0-1)	43% (n = 3/7)	14% (n = 1/7)	4.03 (0.23, 274)	0.559
Subgroup Mortality	0% (n = 0)	13% (n = 1)	‡	> 0.999

SDAC = STRokE DOC Adjudicating Committee; MM = Medical Monitor; CI = Confidence Interval
‡ = No Odds Ratio reported due to sparse data; *P-values are from Fisher's Exact test

Discussion and Conclusions

STRokE DOC Arizona TIME trial has been completed, showing that it is feasible to establish a single hub, multi-rural spoke hospital telestroke research network in Arizona. The feasibility trial was not designed to have sufficient power to detect a difference between the two consultative modes, telemedicine and telephone-only. Overall, the correct treatment decision was established in 87% of the consultations. Both modalities, telephone (89% correct) and telemedicine (85% correct) performed very well. Overall, intravenous thrombolytics were used in 30% of the consultations and post tPA ICH was infrequent. The mean consent to decision durations were not significantly different, 43.7 and 48.6 minutes for telephone and telemedicine respectively. The learning curve was steep for the hub and spokes of this brand new telemedicine network, as reflected by the 74% of telemedicine consults which resulted in a technological issue.

References:

1. Miley ML, Demaerschalk BM, Olmstead NS, *et al.* The State of Emergency Stroke Resources and Care in Rural Arizona: A Platform for Telemedicine. *Telemedicine and e-Health* 2009 (in press)
2. Demaerschalk BM, Miley ML, Kiernan TE, *et al.* Stroke telemedicine. *Mayo Clin Proc* 2009; 84(1):53-64.
3. Meyers BC, Raman R, Hemmen T, *et al.* Efficacy of site-independent telemedicine in the STRokE DOC Trial: a randomized, blinded, prospective study. *Lancet Neurol.* 2008;7:787–795.
4. Capampangan DJ, Wellik KE, Bobrow BJ, *et al.* Telemedicine versus telephone for remote emergency stroke consultations: a critically appraised topic. *The Neurologist.* 2009 May; 15(3):163-166.